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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,647	02/25/2004	Stephen P. Moenning	IPT-02US	2922

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,647	Applicant(s) MOENNING, STEPHEN P.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 11, 15, 16, 21- 22, 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 6-10, 12-14, 17-20 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/04, 6/15/05, 1/15/07, 2/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species 1 (Figs. 1-5), claims 1-2, 6-10, 12-14, 17-20, 23-28 in the reply filed on 2/27/08 is acknowledged.

Claims 3-5, 11, 15-16, 21-22 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species 2-3, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/27/08.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6, 10, 12-14, 20, 23-24, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Melker et al. (US 5,250,038).

Melker discloses a trocar-cannula complex comprising: a trocar /catheter, (also see col. 1, lines 21-30); a fluid delivery cannula comprising a tubular structure including a central lumen 14 receiving the trocar/catheter and an outer surface 20; the fluid delivery cannula further including at least one fluid passage having an inlet port 17 or 25 and an outlet port 19 wherein the outlet communicating with the outer surface 20.

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It has been held that the recitation that an element outer surface is “adapted to interface with tissue at the port site” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claims 2 and 14, a hub portion 23 having a valve 33 being coupled to the fluid delivery cannula.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e “operative to deliver insufflations gas to the patient”, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Beside that, it is well-known in the art to provide a port having valve and connectible with a source of fluid such as insufflations gas. Yoon (US 6,228,068) is one of evidence.

Regarding to claims 6 and 12-13, similarly to rejection of claims 1-2 above, Melker further disclose a fluid delivery cannula comprising a multilayer tubular; at least one fluid passage 14, 15 having an inlet 17, 25, 24; and outlet 19; wherein the fluid passage positioned between two separate layers of tubular structure; the outlet communicating with the outer surface for delivering fluid thereto.

Regarding claims 10, 20, it is noted that the product-by-process limitation “heat shrunk” has not been given weight in determining the patentability of the device claim. See MEPE §2113.

Regarding claims 23-24, they encompass the same scope of the invention as to that of claims 1, 2, 6 except they are drafted in method of performing a minimally invasive surgical procedure instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

Regarding claim 28, the fluid delivered to the inlet by syringe.

Claims 1-2, 6-8, 10, 12-14, 17-18, 20, 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoon (US 6,228,068).

Yoon discloses a trocar-cannula complex comprising: a trocar T, a fluid delivery cannula comprising a multilayer tubular structure including a central lumen 69 receiving the trocar T and an outer

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surface 22; the fluid delivery cannula further including at least one fluid passage having an inlet port 44, the outlet 34 communicating with the outer surface

It has been held that the recitation that an element outer surface is "adapted to interface with tissue at the port site" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claim 6, the fluid delivery cannula further including at least one fluid passage having an inlet and outlet; wherein the fluid passage positioned between two separate layers of the tubular structure (see Fig. 2), the outlet communicating with the outer surface for delivering fluid thereto.

Regarding claims 7 and 17, the tow separate layers include an inner rigid tubular member (16, 18, 68), it is noted that the tubular member has rigid character in some degrees; an outer sheath 22, the inner rigid tubular member including a grooved surface 36, 40 (Fig. 3), 42 (Figs. 5, 13), 66 (Fig. 7), 166 (Fig. 19), 140, 142C (Figs. 18-25) for providing the fluid passage; the outer sheath operative to seal said fluid passage against leakage.

Regarding claims 8 and 18, the outer sheath 22 made of Tecoflex, Teflon, Goretx are polymeric materials (col. 8, lines 46-48).

Regarding claims 10, 20, it is noted that the product-by-process limitation "heat shrunk" has not been given weight in determining the patentability of the device claim. See MEPE §2113.

Regarding claims 23-24, they encompass the same scope of the invention as to that of claims 1, 2, 6 except they are drafted in method of performing a minimally invasive surgical procedure instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 9, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 6,228,068).

Yoon discloses the invention substantially as claimed. Yoon does not specifically disclose the polymeric material includes PTFE.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the outer sheath made of PTFE material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melker or Yoon.

Regarding claims 25-26, Melker or Yoon discloses the invention substantially as claimed. Melker or Yoon does not specifically disclose the fluid includes a pain medication or a tissue adhesive. However, it is well-known in the medical surgery art to provide any drugs (such as pain killer) or a tissue adhesive to help healing quicker to treat in to patient for intended use.

Regarding claims 27-28, Melker or Yoon discloses the invention substantially as claimed. Melker does not disclose the fluid is delivered to the inlet by a pump; or Yoon does not specifically disclose the fluid is delivered to the inlet by a pump or syringe. However, it is well-known in the medical art to use syringe or pump for delivering the drugs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided

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the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 3, 6-10, 12-14, 17-20, 23, 25, 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 12-16, 20-23, 25-28, 34, 37-38 of U.S. Patent Application Nu. 11/464893.

Claims 23-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-40 of U.S. Patent Application No. 11/007,410.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device and method of instant claims are fully disclosed and covered by the claims in the copending application claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763